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# Clinical Needs Discovery in Pediatric Urology: Utilizing the Biodesign Process

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**Introduction:** Biodesign innovation processes provide a needs-driven approach to medical innovation, empowering both medical trainees and health care providers to take action in addressing the shortcomings of health care encountered in daily clinical practice. Our objective was to uncover the most pressing unmet clinical needs within a specific clinical setting, pediatric urology at UCLA.

**Methods:** The biodesign process involves a sequential process of identifying, validating, and prioritizing unmet needs, followed by solution landscaping and prototyping for the most promising needs. Opportunities for medical innovation were first identified through six weeks of clinical immersion, which involved both clinical observation and interview-based insight extraction. Interviews were conducted with 35 stakeholders, including patients, patient families, and health care staff by a medical student participant in Sling Health LA, a program which provides innovation training and incubation for ideas. Follow-up interviews with key stakeholders were performed to validate needs. Priority scores were then assigned to each validated need using a series of pre-determined and weighted criteria. Finally, genealogy maps were constructed and used to guide subsequent solution landscaping for the top three needs.

**Results:** 33 unmet clinical needs were identified throughout the clinical immersion phase, 27 of which were validated. Following coarse needs prioritization, five needs emerged as top contenders. After fine needs prioritization, three top needs were selected. The first top need arising from this ethnographic study was that "parents and children need a faster (<3 months to resolution) treatment option for resolving nocturnal enuresis that also prevents incontinence during the treatment phase". Other discovered top needs included "parents and physicians need an accurate method to monitor retractile testes at-home and in the outpatient setting to reduce unnecessary surgical referrals and procedures", and "a hospital system need to reduce complications and readmissions associated with post-operative catheter obstruction after urologic procedures". A preliminary solution concept was generated for the top clinical need, nocturnal enuresis treatment.

**Conclusion:** Biodesign processes offer a standardized method for identifying pressing unmet clinical needs and informing solution development. The top three needs discovered within pediatric urology through this ethnographic investigation represent promising innovation targets for further solution prototyping and design.

**Keywords:** innovation, BIODESIGN, pediatric urology, Medtech, urology, needs-based, nocturnal enuresis, incontinence

## INTRODUCTION

The Biodesign innovation process was first developed at Stanford University to promote education in medical innovation and shape trainees into biomedical innovators. Using the three principles of “identification, invention, and implementation,” unmet clinical needs are identified and solutions are invented and implemented through a viable business strategy. The Biodesign process follows the sequential and iterative process of clinical immersion, needs identification, needs filtration, needs validation, and solution concept generation to produce tangible biomedical innovations (1, 2).

The Biodesign process is foundationally based on applying a rigorous process to innovation, starting with the development of a deep initial understanding of the unmet clinical needs within a specific field and environment. This process is built upon a thorough and rigorous method for clinical needs discovery and subsequent innovation development (1, 2). Importantly, needs driven innovation ensures that technologies are developed based on a legitimate clinical need and that potential markets exist for solutions before significant investment into innovation development. Since 2001, over 53 biomedical startups have arisen from projects initiated with the Biodesign innovation program at Stanford University alone. Nineteen percent of these companies have been acquired and 67% of companies remain currently active, demonstrating the success of this method for translation to meaningful clinical solutions (3). To date, this work has been less commonly implemented in medical education, though recently has become part of the offerings of UCLA with inclusion in the Sling Health program initiated in summer 2021. Within the context of a six-week summer elective course consisting of didactics, mentorship, and focused clinical immersion, students between their first and second week of medical school learn and apply these techniques to a single clinical area. Learning and applying biodesign-based processes empower students by providing a framework to assess and address observed unmet needs. These skills are readily transferable to any clinical environment and thus offer students a practical and effective means to guide future innovation throughout their careers.

Urology is a technology-driven surgical field, where new innovations have been rapidly welcomed and implemented into common surgical practice. From pioneering the use of robotic surgery and minimally invasive surgical techniques, to new developments in regenerative medicine and tissue engineering, urology is an exciting field that is well-positioned to launch improvements in surgical and biomedical technology

that will be transferable to numerous medical fields (4, 5). In contrast, pediatric innovation has historically been challenging as many barriers exist in the testing and regulation of technologies intended specifically for pediatric use. In pediatric surgery, many new technologies are first developed and approved for adult use, before eventual adaptation for pediatric use. This leaves a gap in solutions for problems that are uniquely pediatric. Thus, pediatric urology was identified as a particularly promising space in which to develop new innovations for unmet clinical needs and was selected for the described focused clinical immersion (6, 7).

Our goal was to apply a stepwise biodesign process in the field of pediatric urology to systematically identify opportunities for medical innovation in a single practice environment while demonstrating the feasibility and outcomes of this process when implemented by a medical trainee. The clinical immersion and needs discovery phases were conducted at pediatric urology clinics in Los Angeles, California as part of a summer medical student immersion program in biomedical innovation. To our knowledge, this is the first publication of the results of a biodesign-based clinical needs discovery process within the field of pediatric urology.

## METHODS

### Clinical Immersion

Clinical immersion was conducted over a six-week period from June 1 to July 13, 2021, at the UCLA Westwood and Santa Monica pediatric urology locations in Los Angeles, California. This study arose from a summer course for medical students at the David Geffen School of Medicine at UCLA. This curriculum was offered by a student organization called Sling Health LA, a chapter within the national organization Sling Health (8), which incubates medical technology ideas of students. The goal of clinical immersion was for medical students to act as a medical ethnographic researcher, directly observing and documenting current clinical practice and scenarios without interfering in the delivery of healthcare. During clinical immersion, observations where an existing clinical process, procedure, or patient encounter may be suboptimal were documented. For example, an ethnographer might shadow a pediatric urologist during regular clinic hours on a Tuesday morning and observe patients sitting in the waiting area and drinking water for over an hour. After observing the waiting area for several more minutes, the ethnographer could learn that children do this in order to supply two separate urine samples to the clinic: one for

urodynamic testing, and another for urinalysis and culture. Seeing an opportunity to cut down on patient wait times, the ethnographer would then record their observation in a notebook, logging the date and time at which it occurred. In addition to direct observation, interviews were conducted with health care staff, patients, and family members to explore unmet clinical needs. There were several goals for stakeholder interviews in this study. The first goal was to interview as many individuals as possible over the six-week clinical immersion period, in order to obtain the greatest number of potential unmet clinical needs and to build student interview and observational skills. The second goal was to outline a broad range of unmet clinical needs by interviewing individuals with different roles on the healthcare team, with the aim for stakeholders to be distributed as evenly as possible across different healthcare staff and parents or patients. The medical student ethnographer requested interviews with stakeholders in-person while engaging in the six-week period of clinical immersion. In total, interviews were conducted with 35 stakeholders. 18 healthcare staff were interviewed, including three physicians (two pediatric urologists, one urology resident), five nurses, two medical assistants, two ultrasound technicians, and six administrative staff, in addition to 17 total family members and pediatric patients (**Figure 1**).

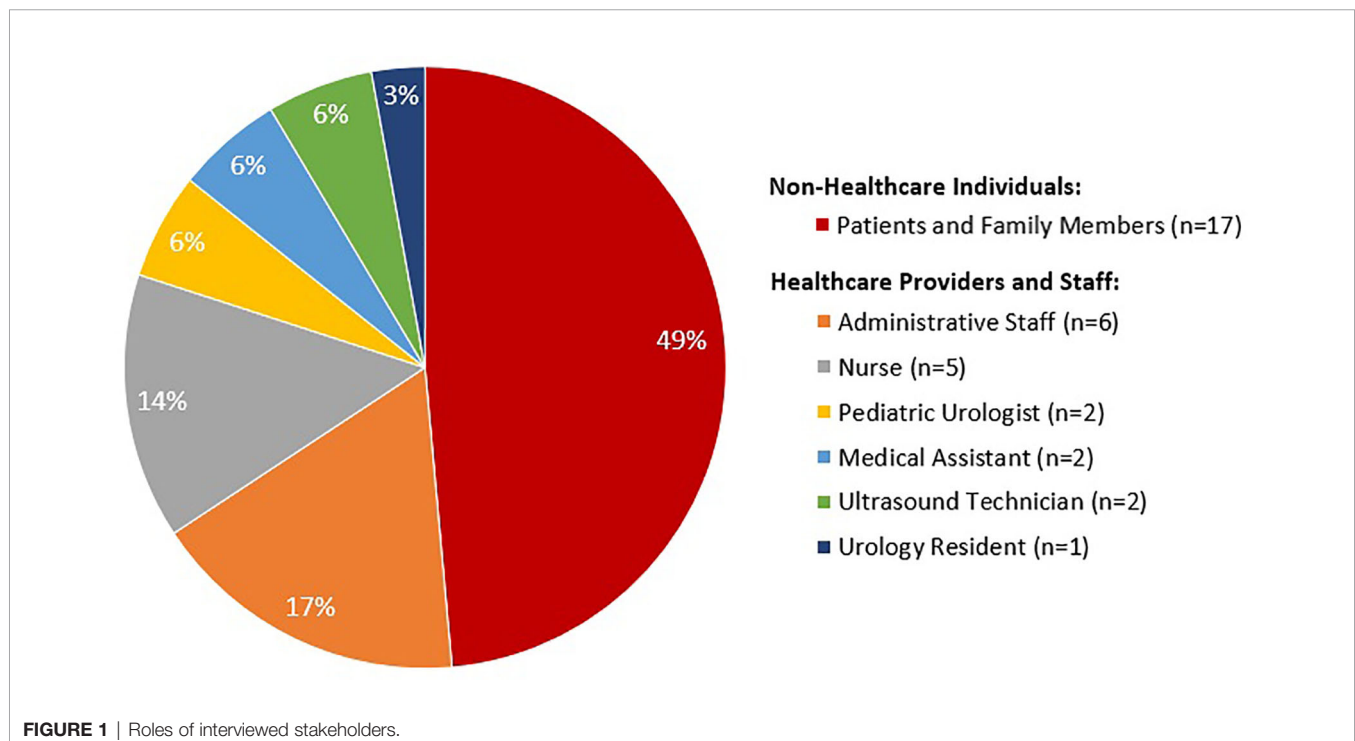
### Needs Validation

Needs validation was continuously performed through repeated clinical immersion and informal follow up interviews with healthcare staff and patients/patient families. This iterative approach was modeled after the Spiral Innovation Model developed at Johns Hopkins University (9). Each direct

observation was translated into a “need statement,” a concise sentence that stated the desired outcome for each clinical need without specifying a particular solution. A need statement classically contains three components: the problem that the statement is addressing, the population that is affected by the problem, and the desired outcome. By design, the solution is initially unspecified to avoid restricting the genealogy mapping and solution landscaping steps implemented later in the process. This ensures that identified innovation targets avoid an early bias toward one particular mode of intervention based on a pre-specified solution embedded within the original needs statement. Need statements were continuously updated based on new insights gained throughout the six-week clinical immersion. Increasing the innovator’s knowledge base in pediatric urology conditions, procedures, and treatments was also emphasized to validate and further refine need statements.

### Needs Prioritization, Selection, and Solution Landscaping

Need statements were prioritized *via* a Pugh decision-making matrix method with pre-determined and weighted scoring criteria (10). Scoring criteria and weighting factors were crafted by the medical student ethnographer with physician mentor input prior to needs prioritization. Overall scoring criteria involved five broad categories: feasibility and ability to solve, risk and investment, impact in pediatric urology or patient experience, market opportunity, and innovator preference (**Table 1**). Needs prioritization consisted of two phases: coarse and fine needs prioritization. For each unmet need, the medical student ethnographer assigned scores for each scoring criteria.



The first phase, coarse needs prioritization, ranked needs by the first three scoring criteria: feasibility and ability to solve, risk and investment, and impact in pediatric urology or patient experience. The five top scoring needs then underwent fine needs prioritization, where needs were ranked by the two additional criteria: market potential and innovator preference. Market potential was assessed by conducting internet searches for existing solutions and analyzing publicly available data such as ease-of-use, device costs, and number of devices sold per year. Literature review was conducted for disease-specific incidence and prevalence information to assess the size of patient populations reached by a potential intervention.

Following needs prioritization, the three needs with the highest scores were selected for genealogy map construction. Genealogy maps illustrate a stepwise method of transforming needs into innovation targets by considering all potential underlying root causes for the problem at hand. Genealogy maps were utilized to assess root causes of each need and served as a scaffold for solution landscaping. In addition to information collected from interviews and observation, an Amazon product search was conducted utilizing the search term “bedwetting alarm” to identify existing devices on the market. Amazon reviews from 2016 - 2022 were extracted from the Amazon marketplace for all bedwetting products with more than 300 ratings. This filtered search resulted in 10 products which were each subsequently reviewed and analyzed for cost and common features. An additional internet search was conducted to assess alternative nocturnal enuresis products on the market, focusing in particular on novel technological devices that differ from classic bedwetting alarms.

## RESULTS

Six weeks of clinical immersion identified a total of 33 unmet clinical needs that underwent subsequent needs validation. Twenty-seven needs were successfully validated and underwent coarse needs prioritization. The top five needs from coarse needs prioritization were then ranked *via* fine needs prioritization (Figure 2). After fine needs prioritization, the top three needs

were determined (Table 2). The first top need arising from this study was that “parents and children need a faster (<3 months to resolution) treatment option for resolving nocturnal enuresis that also prevents incontinence during the treatment phase.” The second top need was that “physicians and parents need an accurate method to monitor retractile testes at-home and in the outpatient setting to reduce unnecessary surgical referrals and procedures.” The third top need revealed “a hospital system need to reduce complications and readmissions associated with post-operative catheter obstruction after urologic procedures.”

Genealogy mapping of the top three needs was performed. Genealogy mapping of the top need revealed several shortcomings of bedwetting alarms, which are the current first-line intervention for nocturnal enuresis (Table 3). Shortcomings include: alarms are ineffective at arousing children directly with children who experience nocturnal enuresis considered difficult to arouse by their parents alarms may unintentionally awaken other household members, children often require assistance to use the alarm correctly, the alarm does not prevent enuresis directly while being used, and prolonged treatment times (>3 months) that are typically required before achieving dry nights.

Root cause analysis of the shortcomings of existing bedwetting alarms was performed to identify preliminary innovation targets. Potential targets for innovation included devising a more effective enuresis signal that would arouse deep sleepers without disturbing additional household members. Other innovation targets included the creation of a device that would prevent voiding while minimally interfering with patient sleep, a device that reinforces neural pathways that promote nighttime continence, and a device that could predict when voiding will occur each night (Table 3).

Market analysis of ten total bedwetting alarms revealed a cost range of \$30-\$300. The most common features of current bedwetting alarms were those to improve child awakening including loud volume, vibration, and lights. Analysis of nocturnal enuresis devices in development or with recent entry to the market additionally identified several novel technologies, including a device that leverages predictive learning of biometric data to sound an alarm before enuresis occurs (11).

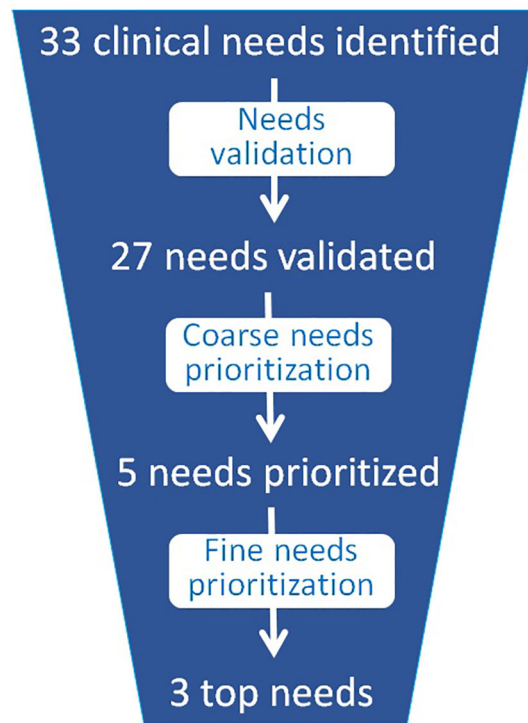
**TABLE 1** | Weighted scoring criteria for decision-making matrix.

### Coarse Needs Prioritization

Criteria	Category	Weight	Scoring Considerations
1	Feasibility and ability to solve	1.0	Needs involving pharmaceutical development and/or needs subject to extensive regulatory considerations received lower scores.
2	Risk and investment	0.6	Needs requiring only incremental solutions and/or institution-specific process changes received lower scores, while complex needs with the potential for radical change received higher scores.
3	Impact in pediatric urology field or patient experience	0.75	Assessment of potential impact was discussed with interviews with expert clinicians.

### Fine Needs Prioritization

Criteria	Category	Weight	Scoring Considerations
1	Market opportunity	1.0	Disease-specific incidence and prevalence data was collected from literature review. Existing solutions and potential for market disruption (existing device costs, number of devices sold per year, etc.) were assessed using publicly available data.
2	Innovator preference	0.5	Needs that the innovator preferred to work on received higher scores.



**FIGURE 2** | Needs identification, validation, and prioritization funnel.

A preliminary solution concept for nocturnal enuresis treatment was developed utilizing the innovation targets that were brainstormed. Based on informal follow-up discussions with clinicians and external research, the most important characteristics to include in our solution concept were to offer a faster (<3 month) treatment option for resolving nocturnal enuresis coupled with prevention of incontinence during the treatment phase. Our solution concept consists of a dual detection-response system with two components: a sensor component and a stimulator component. The sensor system would provide both an *in*

*vivo* non-invasive bladder pressure and/or volume monitoring while patients sleep and would also provide an alarm in the setting of voiding. A direct bladder volumetric individualized machine learning system could additionally be developed to provide pre-void detection. The stimulator system would consist of a neuromodulation-based response system that leverages autonomic control of bladder and sphincter muscles to prevent urination. The goals for the response system would be to temporally stimulate muscle contraction of the pelvic floor or decrease contractility of the bladder in order to prevent urination.

**TABLE 2** | Eight top unmet clinical needs discovered in pediatric urology.

#### Top 8 Unmet Clinical Needs

- 1 Parents and children need a faster (<3 months to resolution) treatment option for resolving nocturnal enuresis that also prevents incontinence during the treatment phase.
- 2 Physicians and parents need an accurate method to differentiate between undescended versus retractile testes at-home and in the outpatient setting to reduce unnecessary surgical referrals and procedures.
- 3 There is a need to reduce complications and readmissions associated with post-operative catheter obstruction after urologic procedures.
- 4 Physicians and patients need better post-op monitoring methods in children and adolescents who have undergone hypospadias urethroplasties to reliably identify long-term complications (e.g. strictures, chordee, fistula) earlier.
- 5 Medical staff and patients need a way to assess both uroflowmetry and urine culture with a single urine sample to improve clinical efficiency and patient satisfaction.
- 6 Patients and their parents need a pediatric monitoring system to track fluid intake in children that requires minimal parental burden and active oversight.
- 7 Parents need a tool to promote discussion and education about hypospadias to reduce stigma and misunderstanding about hypospadias and provide support for parents of children with this condition.
- 8 Pediatric urologists need a reliable way to monitor voiding frequencies, amounts, and symptoms associated with urination in children to inform clinical diagnoses and decision-making.



**TABLE 3** | Genealogy map example demonstrating a root cause analysis of the top discovered clinical need.

Underlying Problems	Root Causes	Innovation Targets
Children who are deep sleepers often do not hear the alarm; additionally, children experiencing bedwetting also are more likely to be deep sleepers.	Deep sleep may be a root cause of bedwetting.	Potential of neuronal pathways to associate bladder filling (stimulation of afferent fibers) with inhibition of micturition reflex, even during deep sleep.
	Alarms are not effective in arousing deep sleepers.	Alarm with more effective sound transmission (e.g. a different sound quality, volume, or placement of alarm) for deep sleepers.
Alarm system is disruptive and burdensome for patients; patients and parents/caretakers lose sleep	Alarms can be heard by others and may unintentionally wake up additional household members.	Consider an "alarm" that is silent, or an alarm that only arouses the child.
	Children experiencing enuresis are often young and require caregiver assistance with waking up after the alarm sounds, emptying their bladder, and cleaning up after nocturnal enuresis has occurred.	Consider a device that does not require adult supervision in order to work effectively.
Moisture sensor alarms wake the child up only once bedwetting has already occurred.	The moisture-sensor alarm does not prevent enuresis while it is used.	Technology that has the power to predict voiding (e.g. machine learning method) with accuracy. Technology that has the ability to prevent voiding itself.
Treatment with bedwetting alarms is a lengthy process; it can take >3 months to see any response and 4+ months to achieve dry nights.	Reliance on a combination of the alarm and an endogenous (pathological) initiation of micturition reflex to eventually naturally inhibit micturition reflex during sleep.	Exogenous inhibition of micturition reflex to strengthen inhibitory neural pathways.

## DISCUSSION

### Biodesign Innovation Processes

Biodesign-based innovation processes offer trainees, clinicians, and other stakeholders a unique, needs driven approach for developing meaningful clinical solutions. Participating in need assessment and validation early in the innovation process allows academic researchers to focus their research early on topics that are clinically impactful. The ability for researchers to quickly screen and select research topics based on clinical relevance and impact opens the doors for increased efficiency and productivity, which may be particularly valuable when adapting to the rapid pace of technological developments worldwide. Similarly, approaching medical innovation using a biodesign-based process may greatly benefit patients when the innovation is developed quickly or is driven by tangible, validated patient needs. For students, structured innovation processes teach those early in their training how to thoughtfully question the norm in clinical settings. All initial observations in the clinical immersion phase are documented with the purpose of promoting big-idea thinking and creative brainstorming without limits, opening opportunities for novel innovations that defy the status quo.

### Innovation Landscape in Pediatric Urology

Pediatric urology is a promising field for developing new innovations for unmet clinical needs. Innovation in pediatrics has lagged behind that of adult urology due to low market incentivization for companies to develop new solutions in a population with a low disease prevalence, considerable regulatory burden and ethical considerations for randomized trials, and limited funding sources for developing medical

devices (6, 7, 12, 13). In 2016, the Food and Drug Administration (FDA) acknowledged the need for medical devices designed for children and cited differences in pediatric anatomy and lack of commercial incentives as barriers to development (14). Specific to pediatric urology, randomized trials comprise only a small fraction of published literature in the field in part due to the relative scarcity and diversity of conditions represented (15). In particular, few randomized trials exist for assessing robotic and minimally invasive procedures (16, 17). Utilizing a stepwise, defined innovations process in pediatric urology and other pediatric fields offers the opportunity for an impactful unmet clinical need with validated market potential to present itself early in the development process, opening the door for innovation acceleration within this field.

### Nocturnal Enuresis: Our Top Discovered Unmet Clinical Need

We discovered three top needs that represent promising innovation targets for further solution prototyping and design. Based on the categorizations and weighting criteria provided, our highest ranked unmet clinical need was to improve treatment options for nocturnal enuresis. Nocturnal enuresis (bedwetting) is the most common urologic complaint in pediatric patients. Five to 7 million children from ages 5-15 are affected by nocturnal enuresis each year, with an estimated 15% of US children affected at age 5. Moisture-sensing bedwetting alarms provide a 70% success rate for achieving long-term dry nights. However, it can take >3 months for families to see any response to these devices, and up to four months for children to achieve dry nights (18, 19). Additionally, alarms require significant cooperation and effort from the family, who often must wake up with their child to

ensure their compliance with the alarm system. Lastly, moisture-sensing bedwetting alarms do not prevent urination at night while the alarm is being used. Detecting nocturnal enuresis before urination occurs, without awakening the patient or their family, with dryness occurring in less than 3 months will reduce burden and improve sleep quality for children and families, while also decreasing clinician burden and clinic office visits. Our preliminary solution concept addresses these concerns and targets all stakeholder needs in this area with an innovation that addresses the shortcomings of current first-line intervention for nocturnal enuresis, bedwetting alarms. To note, there are several high-tech recent innovative devices on the market that offer alternative solutions to the classic bedwetting alarm; most notably there exists a sophisticated alarm device (GOGO Band System) that utilizes predictive learning of biometric data to predict enuresis episodes, thereby decreasing time to continence (11). Our solution concept validates the need informing this device and builds on the concept of the importance of monitoring and active management during the treatment phase, thereby avoiding the previously described negative effects of most current alarm-based systems. In recent years, randomized control trials for transcutaneous tibial nerve stimulation and percutaneous tibial nerve stimulation as treatment options for nocturnal enuresis have emerged, yet to our knowledge, a nocturnal enuresis device that uses electrical stimulation to prevent urination in combination with active bladder monitoring during the treatment phase has not yet entered the market (20, 21).

### Study Limitations

There are several limitations of this study. The present findings require multi-institutional validation, as this investigation was conducted at a single institution. This additional external validation will account for the wide variation in healthcare delivery and patient populations across different institutions. Additionally, the Pugh decision-making matrix relies on innovators to score each unmet need based on their own perceptions of factors such as technical complexity and impact in the field. While these considerations were informed by experts in the field and external research, further stakeholder evaluation across a wider network can assist in mitigating the impact of innovator bias and expertise that may affect ranking of unmet needs. Additionally, although not utilized for this particular study, an additional weighting factor to account for an uneven distribution of interviewed individuals according to their role (e.g. healthcare team stakeholders versus patient/patient family stakeholders) may be implemented in coarse and fine needs prioritization. This additional weighting factor can account for a potential bias toward either healthcare-oriented or patient-oriented perspectives, respectively. It came as little surprise that the top unmet clinical need was patient-centric, given nearly half (49%) of all interviewees were patients and their family members. Indeed, other subgroups of interviewees such as physicians (9%) were relatively less represented, and accordingly represent a population for further study.

### Future Directions

We are currently proceeding with laboratory validation of a developed prototype through partnership with a senior capstone bioengineering team on the UCLA campus, which is anticipated to be followed by a future clinical study to further ensure customer validation and effectiveness of each component of our solution concept. Device efficacy will be evaluated *via* urodynamics and pelvic floor neurologic responses in healthy adults, followed by evaluation in children diagnosed with nocturnal enuresis. The ultimate goal of the solution development phase is to develop a device that will provide a faster and more effective cure for children experiencing nocturnal enuresis and, in so doing, will transform the landscape of devices currently used for disorders involving bladder control and incontinence.

### CONCLUSION

This is the first description of the application of a stepwise innovations process modeled on both the Stanford Biodesign curriculum and the Spiral Innovation Model developed at Johns Hopkins, as administered by Sling Health LA, within the novel clinical setting of pediatric urology. The described process consisted of clinical immersion, needs validation, needs prioritization, needs selection, and solution landscaping within the setting of pediatric urology. Biodesign-based processes provide students early in their clinical training with the skills to identify unmet needs within their environment. These innovation skills can empower students to continue identifying and solving unmet clinical needs throughout their career in any clinical specialty or practice environment, thereby positively impacting both healthcare providers and the communities they serve. Applying this process not only provided a key facet of medical education, but it also led to discovery and description of impactful unmet clinical needs within a focused pediatric surgical field. This has been followed by development of a preliminary solution concept for the top-ranked unmet need: a better treatment option for nocturnal enuresis that will decrease patient awakening, improve urine volume and continence parameters, and minimize the time required to achieve continence. This work demonstrates that a needs-driven approach to medical innovation in pediatric urology not only benefits patients, students, and researchers, but also uniquely facilitates the development of innovative solutions that will be readily translated into clinical practice.

### DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material. Further inquiries can be directed to the corresponding authors.



## ETHICS STATEMENT

Ethical review and approval was not required for the study on human participants, in accordance with the local legislation and institutional requirements.

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